IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

UNITED STATES OF AMERICA; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, THE STATES OF CALIFORNIA, DELAWARE, CONNECTICUT, COLORADO, FLORIDA, GEORGIA, ILLINOIS, INDIANA, HAWAII, MICHIGAN, MONTANA, NEW MEXICO, NEW YORK, NEVADA, TENNESSEE, TEXAS, NEW JERSEY, RHODE ISLAND, OKLAHOMA, WISCONSIN, NORTH CAROLINA, AND MINNESOTA, THE CITY OF CHICAGO AND THE DISTRICT OF COLUMBIA *ex rel.* ELISA DICKSON, RELATOR, Plaintiffs, v. BRISTOL MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S., L.L.C.; SANOFI-AVENTIS U.S., INC.; AND SANOFI-SYNTHELABO, INC., Defendants.	CIVIL ACTION NO. 11-cv-246-DRH-SCW

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

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INTRODUCTION

Relator Elisa Dickson's Second Amended Complaint ("SAC") should be dismissed with prejudice pursuant to Fed. R. Civ. P. 12(b)(1), 12(b)(6), and 9(b) because it presents inadequately pled and legally defective claims that fail to state a proper claim under the federal False Claims Act ("FCA") or any analogous state statutes.

First, Relator fails entirely to state a claim under the FCA. Relator has not and cannot plead that Defendants' conduct violated any express certification of compliance with a statute or regulation that was a prerequisite to government payment. Relator challenges Defendants' promotion of Plavix® for uses that have all been ***approved*** by the United States Food and Drug Administration ("FDA") as safe and effective. Promotions of FDA-approved uses by definition result in lawful claims (not false claims), because federal law mandates that Medicaid and Medicare reimburse for prescriptions for such "medically accepted indications."

Second, even if the SAC alleged false claims (and it does not), they are not claims this Relator can pursue under the FCA. Relator's claims are a transparent re-hash of allegations that were long ago publicly disclosed in government reports, news media, and Plavix® product liability lawsuits. Relator has no direct and independent knowledge of any of those allegations and, as such, Relator's claims are foreclosed by the FCA's public disclosure bar and the Court lacks subject matter jurisdiction over the suit.

Finally, the SAC makes fraud allegations but fails to meet Rule 9(b)'s heightened pleading standard. Relator fails to identify a single false claim submitted to the government as is required by Rule 9(b) and fails to allege the who, what, where, when, and how of either the alleged false statements or any false claim.

BACKGROUND

The FDA approved Plavix® (clopidogrel bisulfate) in 1997 for use as monotherapy (*i.e.*,

without aspirin) in patients with recent heart attack or stroke or diagnosed peripheral arterial disease ("PAD"). The FDA's approval was based, in part, on the results of the CAPRIE clinical trial.[1] As stated in the FDA-approved label for Plavix®, CAPRIE demonstrated an 8.7% relative risk reduction benefit from using Plavix® instead of aspirin across the entire study.[2] It also found that "because aspirin is itself effective in reducing cardiovascular events in patients with recent myocardial infarction or stroke, the effect of Plavix is substantial."[3]

After further studies demonstrated that Plavix® had other significant clinical benefits, FDA approved Plavix® for dual therapy with aspirin for the treatment of patients with acute coronary syndrome ("ACS"), a set of clinical signs and symptoms occurring when the heart muscle does not get enough blood due to plaque narrowing or blocking the arteries leading to the heart. *See* SAC, Ex. B (Plavix® Package Insert), at 2. Physicians widely prescribe Plavix® to reduce the risk of blood clots, which can cause heart attacks or strokes.

Relator Elisa Dickson filed the SAC on November 29, 2012. *See* Second Am. Compl. (Doc. 38). The SAC fails to allege *any* false claims, because it addresses only FDA-approved indications for Plavix®, which the government is required to pay as a matter of law regardless of any promotional claims Defendants may have made, and fails to allege any certifications of

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1 *See* SAC, Ex. B, at 24; SAC, Ex. F (CAPRIE Trial Abstract). *See also* CAPRIE Steering Committee, *A randomized, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE)*, 348 Lancet 1329 (1996) (attached as Ex. A). The Court may consider publicly available information without converting this motion into one for summary judgment. *See, e.g., Pugh v. Tribune Co.*, 521 F.3d 686, 691, n.2 (7th Cir. 2008) ("We may take judicial notice of documents in the public record . . . without converting a motion to dismiss into a motion for summary judgment."); *Hall v. Bristol-Myers Squibb Co.*, No. 06-5203, 2009 WL 5206144, at * 6 (D.N.J. Dec. 30, 2009) (Wolfson, J.) (medical studies attached to a motion to dismiss were properly before the court).

2 SAC, Ex. B, at 24.

3 *Id.* at 25; *see* Ex. A, at 1329, 1336 ("The overall safety profile of [Plavix®] is at least as good as that of medium-dose aspirin" and that "[g]iven this favourable efficacy/safety ratio, [Plavix®] is an effective new antiplatelet agent for use in atherothrombotic disease.").

compliance with a statute or regulation that are a condition of payment for any federal health program. In addition, the SAC's allegations are based entirely on allegations disclosed in prior federal court litigation, news media reports, or FDA reports. The SAC's regurgitation of these old allegations is long on conclusions and short on facts, offering only a series of general allegations that Defendants over-promoted Plavix® as more effective than other drugs by misrepresenting certain clinical studies.[4] Finally, the SAC offers no factual specifics to back up its conclusory allegations and makes no effort to tie these allegations to any reimbursements made or injury suffered by any government payor. Thus:

- Relator does not identify ***who*** made or received the supposed false representations she relies upon. She fails to identify any specific physician, patient, or government payor who received any false information from her or anyone else. Relator fails to allege who at Sanofi instructed her to make allegedly improper promotional statements and makes no allegations at all as to conduct by Defendant Bristol-Myers Squibb Company ("BMS"). Relator's allegations are vague, and in large part her affidavit consists of nothing more than lay opinions on medical issues and pejorative characterizations.
- Relator does not allege ***what*** false statements allegedly caused government payors to reimburse for Plavix®. Relator never alleges that any payor saw the statements in the

[4] Relator alleges that Defendants: (1) promoted Plavix® as superior to aspirin for stroke patients by citing the CAPRIE study's 8.7% relative risk reduction compared to aspirin, *see* SAC ¶¶ 47-50; (2) promoted Plavix® as being just as safe as aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix® to a dose of 325 mg of aspirin which Relator alleges is "not regularly prescribed today," and even though one 2005 study (the "Chan" study) showed that Plavix® caused more gastrointestinal bleeding than aspirin plus esomeprazole in certain patients, *see* SAC ¶¶ 20, 54-57; (3) stated to doctors that the "PRoFESS" study showed that "Aggrenox failed to meet the primary end point of noninferiority for recurrent stroke relative to Plavix®," *see* SAC ¶¶ 21, 58-60; and (4) improperly obtained a label change for Plavix® based on the "CURE" study for patients following coronary artery bypass grafting ("CABG"), *see* SAC ¶ 53.

one sales pamphlet cited, the materials addressed in the FDA reports, or any other supposedly misleading statements, or that any particular doctor wrote a prescription that was reimbursed based on these allegedly false statements.

- Relator fails to state ***when*** any allegedly false statements were made. Nor does the SAC give any indication of when in the 14-year period covered by the SAC any government payor reimbursed for any alleged false claims.
- Relator makes no allegations as to ***where*** allegedly wrongful conduct occurred. Relator does not allege where even one allegedly false promotion was made.
- Relator makes no effort to explain ***how*** these unspecified false statements affected any government reimbursement decision, and does not identify even a single alleged false claim.

In short, Relator alleges millions of dollars in false claims based on long-public assertions of wrongful marketing, and fails to identify any particular physician, patient, or government payor who was influenced to prescribe, use, or reimburse for Plavix® because of Defendants' purported misrepresentations. Not surprisingly, the Federal and state government co-plaintiffs declined to intervene. *See* Declination (Doc. 25).

ARGUMENT

I. THE SAC FAILS TO STATE A CLAIM UNDER THE FALSE CLAIMS ACT

Relator's allegations fail to state a claim under the FCA and should be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, because the SAC is devoid of any facts sufficient to establish that any conduct by Defendants led to the submission of even a single false or fraudulent claim. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."); *Bell Atlantic Corp. v.*

Twombly, 550 U.S. 544, 555 (2007) (factual allegations in the complaint must "raise a right to relief above the speculative level").

To state a claim under 31 U.S.C. § 3729(a)(1), a plaintiff must plead three elements with particularity: "(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with knowledge that the claim was false." *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 741 (7th Cir. 2007), *overruled in part on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 909-10 (7th Cir. 2009). To state a claim under § 3729(a)(2), the relator must plead: "(1) the defendant made a statement in order to receive money from the government, (2) the statement was false, and (3) the defendant knew it was false." *Id.* (internal citations omitted); *United States ex rel. Gross v. AIDS Research Alliance-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005).[5] Only false statements that are material to a government payment decision are actionable under the FCA. *See Gross*, 415 F.3d at 604; *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732-33 (7th Cir. 1999).

Circuit courts have characterized two types of actionable claims under the FCA: factually false claims and legally false claims. *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008). In *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011), the court explained that a "claim is

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[5] In 2009, Congress amended Section 3729(a)(2) and re-designated it as Section 3729(a)(1)(B). *See* Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617, 1621 (2009) (changing language imposing liability on one who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government" to impose liability on one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"). Courts in this Circuit continue to apply the pre-2009 three-element standard for subsection (a)(2) claims to subsection (a)(1)(B) claims. *United States ex rel. Walner v. NorthShore Univ. Healthsystem*, 660 F. Supp. 2d 891, 896 n.4 (N.D. Ill. 2009) (Kendall, J.).

factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." When asserting a "legally false" or "false certification" claim, the relator must allege "that the defendant has 'certifie[d] compliance with a statute or regulation *as a condition* to government payment,' yet knowingly failed to comply with such statute or regulation." *Conner*, 543 F.3d at 1217 (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)) (emphasis in the original); *Gross*, 415 F.3d at 605 ("[W]here an FCA claim is based upon an alleged false certification of regulatory compliance, the certification must be a condition of the government payment in order to be actionable.").

Alternatively, to assert a "factually false claim," the relator must allege "that the government payee has submitted 'an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'" *Conner*, 543 F.3d at 1217 (quoting *Mikes*, 274 F.3d at 697). Relator fails to allege either.

A. Relator's Claims Fail under a "Legally False" or "False Certification" Theory

Relator fails to allege any claim "premised upon an alleged false certification of compliance with statutory or regulatory requirements," and fails to allege that any such "certification of compliance [was] a condition of or prerequisite to government payment." *Gross*, 415 F.3d at 604. *See also United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999). Relator's conclusory allegations that Defendants caused physicians and pharmacists to make false certifications about Plavix®'s efficacy or necessity, *see* SAC ¶ 71, fail to identify any express certification of compliance with a statute or regulation that is a condition of payment under a federal program. *See United States ex rel. Yannacopoulos v. Gen.*

Dynamics, 652 F.3d 818, 824 n.4 (7th Cir. 2011) (citing *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit.")); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 269 (5th Cir. 2010) ("[E]ven if a contractor falsely certifies compliance (implicitly or explicitly) with some statute, regulation, or contract provision, the underlying claim for payment is not 'false' within the meaning of the FCA if the contractor is not required to certify compliance in order to receive payment.").

In *United States ex rel. Ge v. Takeda Pharm. Co.*, No. 10-11043-FDS, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) (Saylor, J.), the court held that "[b]ecause relator has not adequately established that compliance with adverse-event reporting procedures was a material precondition to payment of the claims at issue, the complaints do not state a claim upon which relief can be granted under Rule 12(b)(6)." Here, Relator fails to allege that any FDA marketing or other regulations allegedly violated by Defendants either were coupled with a certification of compliance with such regulations or were a "condition of or prerequisite to government payment." *United States ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 858 (7th Cir. 2006) (quoting *Gross*, 415 F.3d at 604). *See also United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-0704-ERK, 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009) (Korman, J.) ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit.") (internal quotations and citation omitted).

Thus, because none of the claims alleged by Relator contained a certification of compliance with any rule or regulation that was a condition of payment under any government

program, Relator fails to allege a viable false claim and the SAC must be dismissed.[6]

B. Relator Fails to Allege a "Factually False" Claim because Claims Submitted for FDA-Approved Indications of Plavix® Are Not False

Relator also fails to allege a "false or fraudulent claim" because Relator's allegations relate entirely to prescriptions of Plavix® for its FDA-approved indications. SAC ¶ 3 (conceding that this "action arises out of" promotion "for certain indicated usages").[7] Relator asks this Court essentially to overrule the FDA's approval of Plavix® for treatment of stroke patients and to substitute its judgment for the independent medical judgment of physicians who prescribed Plavix®. Relator's allegations are unprecedented. Defendants are aware of no case that has held a drug manufacturer liable for fraud under the FCA for on-label promotion without allegations of illegal kickbacks, which may give rise to liability under a false certification theory.

Relator alleges that Defendants promoted Plavix® by mischaracterizing certain clinical studies to suggest that Plavix® was superior to aspirin to treat stroke patients, *see* SAC ¶¶ 47-52, that Plavix® was as safe as aspirin for stroke patients, *see id.* ¶¶ 54-55, and that a competitor drug was not shown to be as effective as Plavix® for stroke patients, *see id.* ¶¶ 58-60. In each instance, however, the allegations relate to promotion for an FDA-approved, indicated use:

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[6] For the same reasons stated above, Relator's failure to allege any certifications of compliance with any statute or regulation that were express conditions of payment in a government program renders Relator's complaint likewise deficient under the materiality element of the FCA. *See Gross*, 415 F.3d at 604; *Luckey*, 183 F.3d at 732-33.

[7] Moreover, according to Relator's own allegations and the exhibits attached to her SAC, Defendants' promotional statements were true and consistent with the label and the scientific studies on which they relied. For example, Relator alleges that Defendants misused the results of the CAPRIE study by promoting only the overall result for the entire study group and failing to present the subgroup analysis to physicians. SAC ¶¶ 20, 47-50. But CAPRIE was designed and powered to evaluate Plavix®'s efficacy *for the combined subgroups, not for the individual subgroups*. *See* SAC, Ex. B, at 25 ("[T]he CAPRIE trial was not designed to evaluate the relative benefit of Plavix over aspirin in the individual patient subgroups . . . ."); SAC, Ex. F, at 1 ("Long-term administration of clopidogrel to patients with atherosclerotic disease [which includes patients with prior stroke] *is more effective* than aspirin in reducing the combined risk of ischaemic stroke, myocardial infarction, or vascular death.") (emphasis added).

Plavix® for treatment of stroke patients.[8]

These assertions do not allege a false or fraudulent claim because federal law *mandates* federal reimbursement for prescriptions written by doctors for uses approved by the FDA. Medicaid and Medicare are *required* to pay such claims,[9] and there is nothing false about asking the government to pay for amounts it legally owes. *See United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002) ("The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts *it does not owe*.") (emphasis added) (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999)).

In the healthcare context, absent kickbacks, a "false or fraudulent claim" occurs only when Medicaid pays for drugs that "are not used for an indication that is either approved by the Food, Drug, and Cosmetic Act (FDCA) or supported by a drug compendia." *United States v. King-Vassel*, No. 11-236-JPS, 2012 WL 5272486, at *5 (E.D. Wis. Oct. 23, 2012) (Stadtmueller, J.); *United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, No. 03-8239, 2007 WL 2091185, at *2 (N.D. Ill. July 20, 2007) (Kendall, J.) ("Medicaid generally reimburses providers only for 'covered outpatient drugs,'" which "do not include drugs 'used for a medical indication which is

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[8] Relator also alleges on "information and belief" that Defendants obtained an indication for CABG based on the "CURE" study. *Id.* ¶ 53. Relator does not allege any promotional statements made by Defendants regarding the use of Plavix® for CABG.

[9] *See* 42 U.S.C. § 1396r-8(k)(6); *id.* § 1395w-102(e) (Medicare Part D) (setting out limited circumstances -- none applicable here -- in which a state's Medicare or Medicaid program can refuse payment for FDA-approved drugs); *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2010 WL 2649513, at *10-11 (E.D. La. June 29, 2010) (summarizing 42 U.S.C. § 1396r-8(d)(1)(B)). *See also West Virginia ex rel. McGraw v. Eli Lilly & Co.*, 476 F. Supp. 2d 230, 233 (E.D.N.Y. 2007) ("Except in certain narrowly defined situations, states participating in the Medicaid program *must* cover drugs that are subject to [a rebate] agreement between the manufacturer and the federal government.") (emphasis added).

not a medically accepted indication.'") (cited approvingly in *United States ex rel. Tucker v. Nayak*, No. 06-662-JPG, 2008 WL 140948, at *3 n.1 (S.D. Ill. Jan. 11, 2008)).[10] The law is clear that improper promotional messaging that results in the submission of on-label claims, although potentially violative of FDA regulations, does not violate the FCA. *See United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16-17 (D. Mass. 2008) (Saris, J.) (certain off-label marketing allegations not sufficient to establish FCA liability). *See also United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 777-81 (S.D. Tex. 2010) (Rosenthal, J.) (statements in connection with medically necessary claims for reimbursement do not violate the FCA).

United States ex rel. Polansky v. Pfizer, No. 04-0704-BMC, 2012 WL 5595933 (E.D.N.Y. Nov. 15, 2012) (Cogan, J.), is exactly on point. In that case, the relator alleged that Pfizer engaged in an "illegal marketing campaign for Lipitor" that violated the FCA by marketing Lipitor for its FDA-approved use (to lower cholesterol) to patient populations with risk factors and cholesterol levels that did not warrant drug intervention according to the National Cholesterol Education Program Guidelines, which were referenced in the drug's label. *Id.* at *1. The court dismissed the relator's FCA claims because Pfizer was not "doing anything 'false' or [] aiding in the submission of 'false claims' when it markets the drug as effective to patients who fall outside of the Guideline parameters . . . [because] [i]t is marketing the drug, after all, for an FDA sanctioned purpose - to lower cholesterol." *Id.* at *6 ("[A]s long as Pfizer

[10] Even in cases alleging companies engaged in off-label promotion, which is expressly prohibited by FDA regulations, courts dismiss claims where relators fail to allege that Medicaid does not reimburse for the off-label indication. *See United States ex rel. Banignan v. Organon USA Inc.*, No. 07-12153-RWZ, 2012 WL 1997874, at *12-13 (D. Mass. June 1, 2012) (Zobel, J.) (holding that claims are not "false or fraudulent" where the Medicaid program reimburses for the alleged use of the product and dismissing claims of off-label promotion where relator failed to allege that Medicaid refused to cover the off-label indication); *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, No. 09- 1086-AJT, 2011 WL 2182422, at *3 (E.D. Va. May 4, 2011) (Trenga, J.) (dismissal of FCA claims for failure to allege that prescriptions were "not reimbursable under the specific, governing programs and regulations").

markets the drug to lower cholesterol, it is doing what the label permits."). The court stated that because it did not engage[] in off-label marketing," the defendant "has therefore not violated the FCA." *Id.* at *7.

This precedent militates in favor of dismissal here. The SAC alleges only that Defendants are marketing Plavix® for one of its FDA-approved uses: to treat patients who have suffered a stroke. Accordingly, Relator's allegations that Defendants' conduct occurred only in promotion for FDA-approved uses of Plavix® fail to state a claim under the FCA. Furthermore, because Relator fails to allege that either Medicare or Medicaid has prohibited reimbursement of Plavix® for the groups of patients to which Relator alleges Defendants marketed the product for its FDA-approved uses, Relator's allegations do not give rise to FCA liability.

Nor is this Court the place for Relator to challenge the FDA's approval of Plavix® as safe and effective for the uses discussed in the SAC[11] or to challenge the consistency of Defendants' marketing with FDA regulations. "Enforcement of the [Food Drug and Cosmetic Act] is permitted exclusively 'by and in the name of the United States' or, in certain circumstances, by a state." *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 944 (E.D. Wis. 2008) (Stadtmueller, J.) ("[I]ntervention by a court would be tantamount to allowing a private right of action under the FDCA, which the statute does not permit, and because it would violate the directive of the Supreme Court that '[b]ecause agency decisions are frequently of a discretionary nature or frequently require expertise, the agency

[11] Even if it were theoretically possible to plead a false claim based on Defendants having somehow improperly caused the FDA to approve inappropriate Plavix® indications (and as explained in the text it is not), *this* Relator could not do so because she indisputably is not an original source for *anything* having to do with the FDA's approval of Plavix®. She was not even employed by any of the Defendants at the time when the FDA approved Plavix® for use with stroke patients. *See* SAC, Ex. A (Dickson Affidavit), ¶¶ 3-5 (Relator was not employed by BMS until 1999, two years after approval). *See infra* Argument Section II.B.

should be given the first chance to exercise that discretion or to apply that expertise.'") (internal citations and quotations omitted), *amended*, No. 07-642, 2009 WL 151573 (E.D. Wis. Jan. 22, 2009) *and aff'd*, 586 F.3d 500 (7th Cir. 2009); *see also Polansky*, 2012 WL 5595933, at *7 ("False Claims Act cannot be used to circumvent [normal procedures for challenging agency action]" and noting that the FCA was not intended to supplement the enforcement authority of the FDA to regulate drug promotion); *Ge*, 2012 WL 5398564, at *6 (same). Moreover, the FCA is "not designed to reach every kind of fraud practiced on the Government," *United States v. McNinch*, 356 U.S. 595, 599 (1958), and does "not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." *Mikes*, 274 F.3d at 697; *Lamers*, 168 F.3d at 1020 ("[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations."). *See also Wilkins*, 659 F.3d at 310 (relator may not shift the enforcement burden from the FDA, which is "unquestionably better suited than federal courts to ensure compliance with [FDA] regulations."). The SAC, which at most makes allegations regarding violation of FDA regulatory requirements, fails to state a claim under the FCA and should be dismissed.[12]

II. THE COURT LACKS SUBJECT MATTER JURISDICTION BECAUSE THE SAC RELIES ENTIRELY ON PUBLIC ALLEGATIONS MADE IN PRIOR GOVERNMENT REPORTS, NEWS MEDIA, AND LAWSUITS

Relator's claims are prohibited by the public disclosure bar to the FCA, which "block[s] opportunistic lawsuits filed by plaintiffs seeking to capitalize on information already in the public domain." *Glaser*, 570 F.3d at 910. Where -- as here -- the complaint merely re-hashes

[12] Likewise, for the reasons stated above, false promotional statements giving rise to claims submitted for on-label indications of Plavix® cannot be *material* to the government's decision to pay those claims because Medicare and Medicaid pay for all on-label prescriptions regardless of what promotional statements led to their submission. Simply put, the government had no discretion to deny submitted claims under some hypothetical theory of an alleged, unproven FDA violation, and thus Relator's allegations fail to meet the materiality standard.

prior publicly disclosed allegations, the Court lacks subject matter jurisdiction and must dismiss the suit. *See* 31 U.S.C. §3730(e)(4); *Glaser*, 570 F.3d at 909-10. *See also* Fed. R. Civ. P. 12(b)(1).

The public disclosure bar applies where: (1) there has been a "public disclosure" of allegations or transactions, (2) the *qui tam* action is "based upon" such publicly disclosed allegations, and (3) the relator is not the "original source" of the information. *Glaser*, 570 F.3d at 913. Allegations are "'based upon' publicly disclosed allegations or transactions when the allegations in the relator's complaint are *substantially similar* to publicly disclosed allegations." *Id.* at 920 (emphasis added). Relator bears the burden of proving that the suit is not foreclosed by the public information bar. *See id.* While the law was amended in 2010,[13] Relator's suit is barred under both versions of the law because it is based on publicly disclosed information, and she cannot demonstrate that she is the "original source" of the allegations.[14]

A. Relator's Allegations Are Based Upon Public Disclosures

Allegations "substantially similar" to Relator's allegations were previously disclosed in

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[13] As part of the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), Congress amended the public disclosure bar of the FCA on March 23, 2010. Under the pre-2010 version of the statute, the public disclosure bar applies to allegations in "a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media." 31 U.S.C. § 3730(e)(4)(A) (1994) ("pre-2010 FCA"). After the amendment, the bar applies to allegations "publicly disclosed (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. § 3730(e)(4)(A) (2010) ("post-2010 FCA"). The amendment does not apply retroactively to claims submitted prior to March 23, 2010. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 (2010); *see United States ex rel. Osheroff v. Humana, Inc.*, No. 10-24486-SCOLA, 2012 WL 4479072, at *4 n.8 (S.D. Fla. Sept. 28, 2012) (Scola, Jr., J.) ("The previous version of the statute will apply to any alleged false claims made before March 23, 2010, and the amended version to any false claims made thereafter.").

[14] Even if the Court finds that Relator's action is "*even partly based* upon publicly disclosed allegations or transactions [, the action] is nonetheless 'based upon' such allegations or transactions" under the public disclosure bar. *See Glaser*, 570 F.3d at 920 (emphasis added and citation omitted).

news media, federal government reports, or federal product liability suits ("N.J. Suits"):

SAC Allegation	Previous Federal Lawsuits	Previous News Media	Previous Government Reports
Manipulated data from the CAPRIE study to promote Plavix® as superior to aspirin. SAC ¶¶ 3, 8-12; 47-50, 62.	Hall Second Am. Compl. ¶¶ 14-15, 21-24, 29 (Ex. B).	Holleran, *Plavix makers sued in St. Clair County*, Madison-St. Clair Record, Nov. 4th, 2010 (Ex. C).	Div. of Drug Mktg. & Commc'ns ("DDMAC"), Untitled Letter, May 9, 2001.
Downplayed the risk of GI bleeding in Plavix® patients by failing to disclose the findings of the Chan study. SAC ¶ 55.	Ex. B ¶¶ 25-27.	Associated Press, *Study: Plavix® raises risk for ulcers*, St. Petersburg Times, Jan. 20, 2005 (Ex. D); Evans, *Clinical Capsules: Preventing Recurrent Ulcer Bleeding*, Internal Medicine News, Mar. 1, 2005 (Ex. G).	
Misleading promotion of Plavix® concerning a 300 mg "loading dose" and including efficacy claims regarding Plavix® compared to aspirin as documented in FDA untitled letters. SAC ¶ 4-13.	Ex. B ¶¶ 18-21.	Am. Ass'n for Justice, *Lawsuits question safety and efficacy of Plavix*, Trial, March 1, 2007 (Ex. E).	DDMAC, Untitled Letter, Nov. 23, 1998; DDMAC, Untitled Letter, May 9, 2001; DDMAC, Untitled Letter, Mar. 26, 2009.

Exactly like the SAC, the N.J. Suits and media disclosed the allegations that Defendants promoted Plavix® as superior to aspirin,[15] including by allegedly misrepresenting data from the CAPRIE study.[16] For example, the SAC states:

> On May 9, 2001, DDMAC sent another letter to Defendant Sanofi objecting to its promotional efforts for Plavix [regarding the CAPRIE study] . . . . Despite DDMAC's conclusion that "the CAPRIE trial does not provide substantial evidence to support the

[15] *Compare, e.g.*, Second Am. Compl. ¶¶ 23-24, *Hall v. Bristol-Myers Squibb Co.*, No. 06-5203 (D.N.J. May 1, 2009) (attached as Ex. B), *with* SAC ¶ 62. *See also* Comparison Chart of Allegations Regarding Promotion (attached as Ex. F); Kelly Holleran, *Plavix makers sued in St. Clair County*, Madison-St. Clair Record, Nov. 4th, 2010, *available at* http://madisonrecord.com/issues/895-product-liability/231003-plavix-makers-sued-in-st-clair-county (attached as Ex. C).

[16] *Compare, e.g.,* Ex. B ¶¶ 14-15, 21-24, 29, *with* SAC ¶¶ 3, 8-12; 47-50. *See also* Ex. F; Ex. C.

> implication that Plavix has superiority over aspirin," over ten years later Defendants nevertheless continue to promote that Plavix is superior to aspirin despite the fact that no study has generated evidence that supports that claim. SAC ¶¶ 8-12.

The Hall Complaint, contains similar allegations regarding the promotion of Plavix® as superior to aspirin including misrepresenting CAPRIE:

> The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies [including CAPRIE], should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. . . . Still, BMS and Sanofi continued to exaggerate the results of their own studies and to make false statements in their advertising and promotional materials for the purpose of increasing their profit from Plavix sales. Ex. B ¶¶ 14-15.
>
> [T]he Defendants promotional material misled consumers about their own study, called CAPRIE . . . [when] the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin. Ex. B ¶ 21.

Those same allegations were also publicly disclosed in federal reports -- untitled letters from the FDA -- containing allegations of unsubstantiated promotional claims that are identical to the allegations pled in the SAC and the N.J. Suits. The May 2001 letter, which is quoted in both the SAC, *see* SAC ¶ 8, and the Hall Complaint, *see* Ex. B ¶ 21, states:

> [Y]ou present the claim, 'Significant overall risk reduction vs. aspirin 325 mg in CAPRIE, a 3 year study of 19,185 patients.' This claim is misleading because it suggests that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence. As previously stated in our December 18, 1998, untitled letter, the CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superior efficacy over aspirin. Therefore, claims suggesting that Plavix is significantly better than aspirin are misleading because they are not based on substantial evidence.[17]

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[17] Div. of Drug Mktg. & Commc'ns, FDA, Untitled Letter, May 9, 2001, *available at* http://www.fda.gov/downloads/Drugs/ GuidanceComplianceRegulatory Information/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM166467.pdf. *See also* Am. Ass'n for Justice, *Lawsuits question safety*

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Allegations are publicly disclosed where they have appeared in a communication from an agency. *See Gross*, 415 F.3d at 606; *Glaser*, 570 F.3d at 913.[18]

Relator's allegations that Defendants downplayed the risk of gastrointestinal bleeding in Plavix® patients by failing to disclose the Chan study are also substantially similar to allegations in the N.J. Suits[19] and media reports[20] and thus are based on public disclosures. The SAC states:

> [I]n a study published in the January 20, 2005 New England Journal of Medicine (the "Chan Study"), Plavix was shown to cause significantly more gastrointestinal bleeding than aspirin plus esomeprazole (brand name Prilosec) in patients with a history of aspirin-induced ulcers. The Chan Study showed that switching patients to Plavix if they have ulcers with aspirin is not safe, and that it would be cheaper to simply add esomeprazole (an inexpensive over the counter medication) to aspirin. The results of the Chan Study were not disclosed to prescribing neurologists. SAC ¶ 55.

The Hall Complaint contains similar allegations regarding the Chan study:

> Defendants' nearly eight-year run of lying to physicians and the public about the safety and effficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies . . . .
>
> The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In

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and efficacy of Plavix, Trial, Mar. 1, 2007, *available at* http://www.thefreelibrary.com/Lawsuits+question+safety+and+efficacy+of+Plavix.-a0161024365 (attached as Ex. E).

[18] The SAC cites to two additional untitled letters issued by FDA regarding the marketing of Plavix®. SAC ¶ 4-13. The 1998 and 2009 letters concern off-label promotion of Plavix® for stent patients and failure to provide risk information in sponsored internet links. To the extent Relator alleges a scheme of fraudulent promotion based on these letters -- one of which was also cited and relied upon in the N.J. Suits -- her allegations are precluded by the public disclosure bar. *See Gross*, 415 F.3d at 606; *Glaser*, 570 F.3d at 913.

[19] *Compare*, *e.g.*, Ex. B ¶¶ 25-27, *with* SAC ¶¶ 54-55. *See also* Ex. F.

[20] *See*, *e.g.*, Associated Press, *Study: Plavix raises risk for ulcers*, St. Petersburg Times, Jan. 20, 2005, *available at* http://www.sptimes.com/2005/01/20/Worldandnation/Study__Plavix_raises_.shtml (attached as Ex. D); Jeff Evans, *Clinical Capsules: Preventing Recurrent Ulcer Bleeding*, Internal Medicine News, Mar. 1, 2005, *available at* http://www.internalmedicinenews.com/news/across-specialties/single-article/clinical-capsules/88286fa2b3fda368692e2abf0c8dab24.html (attached as Ex. G).

> that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin.
>
> The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than paying for a four-dollar ($4) a day Plavix pill that greatly increases the risk of stomach bleeding. Ex. B ¶¶ 25-27.

B. Relator Is Not an Original Source of the Allegations

The SAC is thus based on publicly disclosed information and can proceed only if Relator demonstrates that she is the "original source" of the information upon which the allegations in the SAC are based, a showing that requires proof that Relator had "direct" and "independent" knowledge of fraudulent activity. *Glaser*, 570 F.3d at 921. Relator must show that she "would have learned of the allegation or transactions independently of the public disclosure," *United States ex rel. Feingold v. Adminastar Fed., Inc.*, 324 F.3d 492, 497 (7th Cir. 2003) (describing "independent knowledge" requirement) and must "establish that h[er] knowledge of the wrongdoing was based on h[er] own investigative efforts and *not* derived from the knowledge of others." *Glaser*, 570 F.3d at 917 (describing "direct knowledge" requirement).

Relator cannot demonstrate she is an original source under the pre-2010 version[21] of the FCA because she fails to show how and when she obtained direct and independent knowledge of the alleged fraud. *See United States ex rel. Hafter v. Spectrum Emer. Care, Inc.*, 190 F.3d 1156,

[21] The 2010 amendment also modified the "original source" definition to include: "an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B) (2010).

1162 (10th Cir.1999) ("[A] *qui tam* plaintiff must allege specific facts--as opposed to mere conclusions--showing exactly how and when he or she obtained direct and independent knowledge of the fraudulent acts alleged in the complaint and support those allegations with competent proof").[22]

Here, Relator has not even pled the alleged fraud with the requisite specificity, *see infra* Section III, let alone pled enough facts to allow the Court to determine how and when she learned of the alleged fraud. *See Stennett v. Premier Rehab. Hosp., LLC*, No. 08-782, 2011 WL 841074, at *1, 7 (W.D. La. Mar. 7, 2011) (Foote, J.), *aff'd*, 479 Fed. App'x. 631(5th Cir. 2012) ("factual allegations fail[ed] to allege, with the specificity required by Rule 9(b) . . . that Plaintiff [wa]s the 'original source' of the information forming the basis of the complaint"); *United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 674-75 (8th Cir. 2003) (holding Relator did not adequately plead the circumstances of the alleged fraud under Rule 9(b)).

Courts routinely find that relators do not qualify as original sources when they fail to allege facts showing direct and independent knowledge of an alleged fraud. *United States v. ITT Educ. Servs., Inc.*, No. 07–00867-TWP-MJD, 2011 WL 3471071, at *7 (S.D. Ind. Aug. 8, 2011) (Pratt, J.) (general knowledge of employers' practices inadequate when relator failed to allege direct knowledge of fraud and facts evidencing the alleged scheme to intentionally and

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[22] The result is no different under the post-2010 FCA, which requires that a relator have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions . . . ." 31 U.S.C. § 3730(e)(4)(b) (2010). As explained below, Relator has failed to allege sufficient facts to demonstrate that she had knowledge independent of the publicly disclosed allegations. Moreover, Relator's allegations also fail to add materially to the prior public allegations because -- after setting aside previous publicly disclosed information -- Relator's SAC contains no facts that would be sufficient to form the basis of a claim under the FCA. *See Osheroff*, 2012 WL 4479072, at *12 (finding relator was not original source when non-publicly disclosed allegations were insufficient to support claims under the Anti-Kickback Statute, the Civil Monetary Penalties Law, or the FCA). *See also United States ex rel. Davis v. Dist. of Columbia*, 679 F.3d 832, 838 n.4 (D.C. Cir. 2012) (explaining that the 2010 amendments require relators to provide information that "adds value" to publicly disclosed information).

knowingly deceive the government). In *ITT*, the relator worked as a recruiter for the defendant and alleged that she was paid based on fulfillment of enrollment, application, and start goals for the school in violation of regulations to which the school certified compliance. *Id.* at *1, *6. But because relator failed to allege "knowledge regarding both the employment evaluation practices of ITT and the payment scheme that ITT utilized for financial aid administrators," the court held that she lacked direct and independent knowledge of the "facts related to the overall claim of fraud and facts that evidence ITT's alleged scheme to intentionally and knowingly deceive the Department of Education." *Id.* at *6-7. Accordingly, the court held she was not an original source and dismissed her claim under the public disclosure bar. *Id.* at *7.

Like the relator in *ITT*, Relator fails to allege the basic facts necessary to support a finding that she is an original source. Nowhere does Relator allege that she has any direct or independent knowledge of any false statements made to any particular physician or of any given physician actually prescribing Plavix® instead of aspirin as a result of the alleged promotional scheme. *See Hafter*, 190 F.3d at 1162 (unsupported, conclusory allegations that relators had direct and independent knowledge were insufficient to establish jurisdiction); *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 475-76 (2007) (relator had no direct or independent knowledge that false statements were made); *ITT Educ. Servs., Inc.*, 2011 WL 3471071, at *6-7 (relator had no direct and independent knowledge of any false claims); *Feingold v. Associated Ins. Cos.*, No. 98-4392, 2001 WL 1155250, at *11 (N.D. Ill. Sep. 28, 2001) (Guzman, J.) (same). Thus, although Relator contends she was instructed to promote Plavix® as superior for aspirin, Relator fails to plead the necessary direct or independent knowledge of Defendants' alleged fraudulent scheme.

In addition, Relator has not pled how and when she learned that Defendants allegedly

manipulated clinical trial data to conceal the asserted fact that Plavix® is not more effective than aspirin for its indicated uses, or that Plavix® is not an effective treatment for stroke patients. Thus, she cannot be the original source of those allegations. *See ITT Educ. Servs., Inc.*, 2011 WL 3471071, at * 6-7 (relator not an original source when she did not know the alleged conduct was in violation of the applicable regulations while she was at the company). Most of Relator's affidavit consists not of facts within her knowledge as a former sales representative, but her opinions on scientific issues concerning the design and interpretation of certain clinical studies. But she never claims to have worked for the Defendants in any medical capacity, or that she was involved in any way in the design of CAPRIE -- or any other study, for that matter. *See United States ex rel. Feldstein v. Organon, Inc.*, 364 Fed. App'x 738, 743 (3d Cir. 2010) (relator did not have independent knowledge of alleged misrepresentations when he was not involved in approval process for drug).

Thus, Relator has not alleged independent and direct knowledge of the key component of her alleged false claim: that Defendants' representations about the results of the CAPRIE or Chan studies were false. Indeed, she nowhere alleges that she was aware of the supposed falsity of the alleged promotional material at any point during her time detailing Plavix® or at any time prior to the public disclosures or that Defendants knowingly promoted Plavix® to deceive doctors to make purported false certifications. Without this information, the Court cannot conclude that Relator has direct and independent knowledge that Defendants' promotion was false. *See Feingold*, 2001 WL 1155250, at *11 (relator had no knowledge of allegedly fraudulent claims that was independent of public disclosures).

Relator's failure to plead facts explaining how and when she learned of these allegations means that she has not met her jurisdictional burden to prove she is an original source. *See*

Glaser, 570 F.3d at 922 (relator did not establish she had independent knowledge of her allegations). Significantly, Relator's counsel previously represented plaintiffs making substantially similar allegations in two product liability suits filed prior to this action. In those prior suits, plaintiffs alleged that Defendants: (1) manipulated data from the CAPRIE study to falsely promote Plavix® as superior to aspirin;[23] (2) downplayed the risk of GI bleeding in Plavix® patients by failing to disclose the findings of the Chan study;[24] and (3) mispromoted Plavix® concerning a 300 mg "loading dose" and including efficacy claims regarding Plavix® compared to aspirin, as documented in FDA untitled letters.[25] Given the similarity of Relator's allegations to the prior lawsuits filed by her counsel, it is reasonable to assume that Relator learned of the allegations through her attorney, and thus does not qualify as an original source.[26] *See Glaser*, 570 F.3d at 921-22 (relator was not an original source when she learned of allegations from her attorney); *Schultz v. Devry Inc.*, No. 07 C 5425, 2009 WL 562286, at *4 (N.D. Ill. Mar. 4, 2009) (Conlon, J.) (same); *United States ex rel Lopez v. Strayer Educ., Inc.*, 698 F. Supp. 2d 633, 644 (E.D. Va. 2010) (O'Grady, J.) (same).

Finally, Relator cannot allege that she has any direct or independent knowledge as to any activities by BMS because she was employed there only beginning in 1999, alleges no conduct

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[23] *Compare* SAC ¶¶ 3, 8-12, 47-50, 62, *with* Compl. ¶¶ 46-47, 53-56, 61, *Davidson v. Bristol-Myers Squibb Co.*, No. 10L-544 (Ill. Cir. Ct. Oct. 15, 2010) (attached as Ex. H), *and* First Am. Compl. ¶¶ 15-16, 22-25, 30, *Mills v. Bristol-Myers Squibb Co.*, No. 2011-000415 (Az. Sup. Ct. Jan. 19, 2011) (attached as Ex. I).

[24] *Compare* SAC ¶ 55, *with* Ex. H ¶¶ 57-59, *and* Ex. I ¶¶ 26-28.

[25] *Compare* SAC ¶¶ 4-13, *with* Ex. H ¶¶ 49-53, *and* Ex. I ¶¶ 18-22.

[26] To the extent that the Court is inclined to find that Relator is an original source, Defendants respectfully request limited jurisdictional discovery regarding Relator's direct and independent knowledge. *See, e.g.*, *United States ex rel. Davis v. Prince*, 753 F. Supp. 2d 569, 576-77 (E.D. Va. 2011) (Ellis, III, J.) (limited jurisdictional discovery to determine whether relator's claims were barred by the public disclosure provision); *In re Natural Gas Royalties*, 562 F.3d 1032, 1037-38 (10th Cir. 2009) (same). *See also Murray v. City of Chicago*, 634 F.2d 365, 366 n.3 (7th Cir. 1980) ("[D]iscovery in limine may sometimes appropriately be limited to jurisdictional questions.").

by BMS or any of its employees, and does not allege that she even performed work related to Plavix® while employed by BMS. *See* SAC, Ex. A ¶¶ 4-5; *United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 352-53 (4th Cir. 2009) (relator was not employed by the defendant). *See also Rockwell*, 549 U.S. at 475 (relator was not employed by defendant during period of relevant conduct). Thus, any claims against BMS should be dismissed for this reason as well.[27]

Because Relator's SAC is based upon publicly disclosed allegations for which she is not an original source, the Court lacks jurisdiction to hear the claims. The Court should, accordingly, dismiss these publicly disclosed claims in their entirety.

III. RELATOR'S CLAIMS LACK THE PARTICULARITY REQUIRED BY RULE 9(B)

Relators alleging fraud under the FCA must plead "with particularity, the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003). To meet this standard, a relator must plead the "who, what, when, where, and how" of the fraud. *Garst*, 328 F.3d at 376 (relator must "(1) identify specific false claims for payment or specific false statements made in order to obtain payment; (2) if a false statement is alleged, connect that statement to a specific claim for payment and state who made the statement to whom and when; and (3) briefly state why those claims or statements were false").[28] Here, Relator fails to meet these requirements.

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[27] For the same reason, at the very least, the Court must dismiss claims for the time period during which Relator was not employed as a Plavix® sales representative at Sanofi. SAC, Ex. A ¶¶ 4-5 (Relator promoted Plavix® from 2003-2005 and 2008-2010).

[28] Relator's conspiracy allegations fail to state a claim upon which relief can be granted because she does not identify any agreement between the Defendants to defraud the government for the purpose of receiving payment. To survive a motion to dismiss, "a relator must allege that the defendants had an agreement or formed a combination to defraud the government and that the defendants did so for the purpose of obtaining payment from the government." *United States ex rel. Wildhirt v. AARS Forever, Inc.*, No. 09-1215, 2011 WL 1303390, at *6 (N.D. Ill. Apr. 6, 2011) (Feinerman, J.) (relator alleged "in a most conclusory fashion" that defendants "conspired to defraud" the government "by getting a false or fraudulent claim allowed or paid."). Here,

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A. Relator Fails to Identify Even a Single False Claim Allegedly Presented for Payment because of Defendants' Conduct

The SAC must be dismissed because it fails to allege a single false claim for payment, let alone identify "(1) who submitted the false claim, (2) what the person submitted, (3) when he submitted the claim, (4) where he did so and (5) how he did so." *See Ortho-McNeil*, 2007 WL 2091185, at *3.

Courts in the Seventh Circuit routinely dismiss complaints for failure to allege that particular false claims were submitted to the government for payment. *Fowler*, 496 F.3d at 741-42 ("Relators do not present any evidence at an individualized transaction level to demonstrate that Caremark failed to provide an appropriate refund or replacement product for a returned prescription."); *Tucker*, 2008 WL 140948, at *3 ("The relator failed, however, to attach a bill, claim, Form-1500 or payment and failed to identify the amount of any charge or the date of any claim."); *United States ex rel. Stone v. OmniCare, Inc.*, No. 09-4319, 2012 WL 5877544, at *1 (N.D. Ill. Nov. 20, 2012) (Zagel, J.) (dismissing allegations that "are not at the *'individualized transaction level'* required of such claims") (quoting *Fowler*, 496 F.3d at 741-42); *United States ex rel. Liotine, CDW Gov't, Inc.*, No. 05-33-DRH, 2009 WL 3156704, *3 (S.D. Ill. Sept. 29, 2009) (relator "cannot rely on the mere probability that a false claim occurred but must at least identify one false claim that was submitted").

Relator's failure to allege any detail identifying a claim submitted by any doctor or pharmacy for reimbursement of Plavix® to Medicare or Medicaid thus requires dismissal here.

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Relator fails to plead "who agreed with whom, how they agreed, how they decided to file a false claim, who made the alleged misrepresentation, who filed the allegedly false claim, the method by which it was filed, and how much the payment was for." *Walner*, 660 F. Supp. 2d at 898. Relator's conspiracy count must be dismissed.

B. Relator Fails to Allege the Who, What, When, and Where of the Fraud

In addition to failing to allege even a single false claim, Relator utterly fails to link any alleged false statements to a particular claim for payment. *See Garst*, 328 F.3d at 378; *Tucker*, 2008 WL 140948, at *4 ("Evidence of a concrete claim actually submitted is required to link [defendant's] conduct with a false claim for payment from the United States, the crux of an FCA case."). Nor does she allege the who, what, when, and where of the alleged fraud. *Ortho-McNeil* is on point and dismissed on Rule 9(b) grounds because:

> [the relator] does not identify which sales representatives made the statements, when they made them, to which doctors they made them or how they communicated them. Nor does [relator] identify which executives at [defendant company] told sales representatives to make these false statements. At best, [relator] describes the general subject of the alleged misrepresentations (Levaquin and Ultram should be used for non-FDA approved uses) and the general category of individuals (sales representatives) who made them. Such generalized allegations are insufficient where "they do not even hint at the identity of those who made the misrepresentations, the time misrepresentations were made, or the places at which the misrepresentations were made."

2007 WL 2091185, at *4 (quoting *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 923 (7th Cir. 1992)).

Here, Relator similarly fails to identify one single physician to whom a particular misrepresentation was made, any instance in which she or any other sales representative made any alleged misrepresentation, any physician that prescribed the drug as a result of such misrepresentation, any Medicare beneficiary that received and filled such a prescription, or any pharmacist that filled such a prescription. Moreover, Relator fails to allege any employee(s) at Defendants who directed her to make any false statements. Rather, Relator alleges general "instructions" to its sales force and unspecified "pamphlets." *See* SAC ¶¶ 19-22. Relator fails entirely to allege that BMS provided such vague instructions to its sales representatives, about

whom Relator provides **no** allegations. Relator also insufficiently alleges "upon information and belief" that Defendants "misled physicians" but fails to identify any promotional activity, let alone anything improper, regarding Defendants' alleged promotion of Plavix® for CABG patients.[29] *See* SAC ¶ 53. Thus, the SAC entirely fails to allege the requisite who, what, when, where, and how of the alleged fraud, and should be dismissed.

IV. RELATOR'S STATE LAW CLAIMS SHOULD BE DISMISSED

Relator's claims based on the false claims and Medicaid claims statutes of 26 different states or localities that are substantively similar to and/or track the language of the federal False Claims Act must likewise be dismissed, for all the reasons set forth above, and for "fail[ure] to comply with the qui tam provisions of the state false claims acts."[30] *United States ex rel. Fowler v. Caremark RX, Inc.*, No. 03-8714, 2006 WL 1519567, at *5 (N.D. Ill. May 30, 2006) (Conlon, J.). Relator's Illinois[31] and Chicago[32] claims are separately deficient.

* * * * * * * * *

For the foregoing reasons, Relator's SAC should be dismissed with prejudice.

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[29] Relator's factual assertions "upon information and belief" are insufficient to satisfy the pleading requirements under Rule 9(b). *See Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442-43 (7th Cir. 2011) (pleading mere "information and belief" cannot satisfy Rule 9(b)); *United States ex rel. Lusby v. Rolls-Royce Corp.*, No. 03-0680-SEB/WTL, 2007 WL 4557773, at *6 (S.D. Ind. Dec. 20, 2007) (Barker, J.) (same) (cited approvingly in *Tucker*, 2008 WL 140948, at *3 n.1 (S.D. Ill. Jan. 11, 2008)).

[30] Relator fails to allege she provided all material evidence in support of her claims or served her complaint on any state other than Illinois. The co-plaintiff states also have public disclosure bars parallel to the Federal FCA, which similarly bar Relator's case under state law.

[31] Relator's claims under the Illinois Public Assistance Fraud Act, 305 Ill. Comp. Stat. Ann. 5/8A-1, *et seq.*, should also be dismissed because Illinois has not intervened and that statute does not provide for a private right of action. 305 Ill. Comp. Stat. Ann. 5/8A-7(c) ("Civil recoveries provided for in this Section may be recoverable in court proceedings initiated by the Attorney General or, in actions involving a local governmental unit, by the State's Attorney.").

[32] Relator's claims based on the City of Chicago False Claims Act should be dismissed because Relator does not allege that Defendants are city contractors. *See* Chicago Mun. Code § 1-22-040(b). *See also Chi. Fire Fighters Union, Local 2 v. Tebbens*, No. 07-2102, 2007 WL 2893002, at *4 (N.D. Ill. Sept. 28, 2007) (Guzman, J.) (plaintiff could not state a claim where defendants were not city contractors).

Dated: December 20, 2012

Respectfully submitted,

By *__/s/ W. Jason Rankin*

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CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2012, a true and correct copy of the foregoing was filed electronically with the Clerk of the United States District Court and forwarded electronically to all counsel.

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